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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/467,317	12/20/1999	RANDOLPH NOELLE	012712-813	2231

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EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/467,317	NOELLE, RANDOLPH
	Examiner	Art Unit
	Phillip Gambel	1644

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *9/30/05; 2/1/06*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *83-86 and 90-94* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *83-86, 90-94* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's Response to Notice Of Non-Compliant Amendment, filed 2/1/06, is acknowledged.

Upon review as applicant notes, claims 57-58, 67 and 69-70 have been canceled and therefore, applicant amendment, filed 9/30/05, was fully responsive.

The examiner apologizes for any inconvenience to applicant in this matter.

2. Claims 1-82 and 87-89 have been canceled.

Claims 83-86 and 90-94 are pending.

3. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.
This Action will be in response to applicant's arguments, filed 9/30/05.
The rejections of record can be found in previous Office Action, mailed 3/30/05.

4. This is a rejection under 35 USC § 112, first paragraph, "written description" (and not new matter).

Claims 83-86 and 90-94 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed.

Applicant's arguments, filed 9/30/05, have been fully considered but have not been found convincing essentially for the reasons of record.

Applicant submits that there is a complete written description of the claimed antigen recognized by antibodies of the invention based upon structural and functional characteristics expressly set forth in writing in the specification.

With respect to applicant's arguments relying upon certain legal decisions concerning the written description of antibodies,
applicant is reminded that the written description rejection is applied to the "antigen" and not to the "antibody" recited in the instant methods.
Therefore, applicant's reliance on written description issues as it applies to the antibody of the claimed does not necessarily satisfy the written description issues as they apply to the genus of targeted "antigens" encompassed by the claimed methods.

Applicant asserts that the skilled artisan would appreciate that the invention has possession of any antigen that binds the CD40-Ig construct and relies upon specific Examples of T cell antigens bound by CD40Ig provided by the application as filed.

While applicant correctly notes that the claims do not recite CD40CR, clearly the present invention relates to a counter-receptor, termed CD40CR for the CD40 B cell antigen (see Introduction and Summary of the Invention on pages 1-2 of the instant specification).

For example as pointed out previously, applicant's submission that at the time of filing of the instant application, CD40CR had been described in several species, including Hollenbaugh et al. (EMBO J 11: 4313-4321, 1992) and Spriggs et al. (J. Exp. Med 176: 1543-1550 (1992) as not found convincing in that neither Hollenbaugh et al. (EMBO J 11: 4313-4321, 1992) nor Spriggs et al. (J. Exp. Med 176: 1543-1550 (1992) were disclosed in the application as filed.

Also, as indicated previously, the size of the 39 kD protein identified as the CD40 binding protein that is selectively expressed on the membranes of activated but not resting T helper cells in the specification as filed (e.g. see Sections 6.2.3-6.2.4-6.3 on pages 28-31 of the specification) differs from those reported for human CD40L (e.g. see Hollenbaugh et al. of record).

Also, noted for example, Hollenbaugh et al., which was co-authored by inventor Noelle isolation and characterization of a human gp39 via screening with oligonucleotides based upon murine gp39 sequences derived from Armitage et al. Nature 357: 90-92, 1992 (1449; of record) (see page 4314, column 1, Isolation and characterization of a cDNA encoding human gp39 of Hollenbaugh et al.).

With respect to human CD40L,
the Example on page 31 of the instant specification appears to be limited to immunofluorescence binding studies with CD40Ig on human T cell lines. These immunofluorescence binding studies were not conducted on activated human T cells. Further, there does not appear to be isolation nor characterization of a human antigen in the specification as filed and, in turn, written description of a human CD40CR / CD40L as the targeted antigen in the instant methods.

Therefore, it appears that when the inventor Noelle isolated human CD40L, materials such as appropriate probes not disclosed in the instant application as filed were employed.

Also, in characterizing the 39 kD as a single chain molecule and comparing it with other known CD proteins, page 30, paragraph 2 of the instant specification discloses that "it is therefore suspected that the 39 kD protein is not one of these CD proteins.

This further indicates that characterization was not complete as it read on the genus of CD40CR / CD40L encompassed by the claimed invention.

For example, it is noted that that last paragraph of Armitage et al. indicated that cloning of the human homolog was not yet isolated at the time the instant application was filed (i.e. priority date of 2/14/92).

Rather than speculate on different possible outcomes either in Regents of the Univ. of Ca. v. Eli Lilly & Co. 119 F.3d 1559 (Fed. Cir. 1997; Lilly) on in Noelle v. Lederman, 69 USPQ2d 1508 (Fed. Cir. 2004; Noelle) as applicant has done,
the rejection of record is consistent with the findings of Noelle and the Written Description Guidelines as well as other legal holdings, that applicant was not in possession of the genus of "antigens" as currently recited in the claimed methods.

Applicant's assertions that the art following a review of the disclosure of the instant. application would conclude that the applicant was in possession of the necessary common attributes possessed by antibodies that bind to the claimed CD40CR "antigen", currently recited is not consistent with the requirements under 35 USC 112, first paragraph, written description as well as the holdings of the Federal Circuit in addressing the written description of CD40CR in parent application USSN 07/742,480. See Noelle v. Lederman, 69 USPQ2d 1508 (CAFC 2004).

While it is acknowledged that the claims of Noelle and the instant application differ, the present case concerns essentially the identical issue of law based on essentially the same prior art / factual basis decided in Noelle. Given the facts are the same or nearly the same in the instant application as the facts in the preceding appeal of USSN 08/742,480, previously decided points of law should be followed unless overruled and the application of the law to the particular facts should be consistent from case to case. The law of the case stands for the principle that issues once decided in a case should not be redetermined.

The law of the case doctrine is limited to issues that were actually decided, either explicitly or by necessary implications, in the earlier litigations.
See Alpha/Omega Ins. Servs. Inc. v. Prudential Ins. Co. of Am. 272 F.3d 176, 179 (5th Cir. 2001) cited by Toro Co. v. White Consolidated Industries Inc., 72 USPQ2d 1449, 1456 (CAFC 2004).

Further, it is noted that priority application USSN 08/742,480 was party to an Interference with the United Stated Patent and Trademark Office Board of Patent Appeals and Interferences (Interference No. 104,415). See Noelle v. Lederman, 69 USPQ2d 1508 (CAFC 2004).

With respect to the disclosure of antibodies that bind a genus of CD40CR antigens, including human CD40CR; the Court affirmed the decision by the Board supported by substantial evidence and the law which held that the USSN 08/742,480 application lacked written description for the genus of CD40CR antigens, including human CD40CR antigen.

Given the state of the art in the early 1990's described by the expert witnesses and evidence, the Court also affirmed the decision by the Board by finding that one skilled in the art would have lacked a reasonable likelihood of success in isolating human CD40CR antigen given mouse CD40CR antigen, including consideration of Noelle's reliance on various screening methods disclosed in the specification.

Applicant has not disclosed "a fully characterized antigen" as it reads on human CD40CR antigen or the genus of CD40CR antigens encompassed by the claims.

There is insufficient written description encompassing the claimed "antigen" specificity because the relevant identifying characteristics such as structure of other physical and/or chemical characteristics of the claimed "antigen" (i.e. "CD40CR") are not set forth in the specification as filed, commensurate in scope with the claimed invention.

Applicant has not satisfied coupling a disclosed correlation between function and a structure that is sufficiently known or disclosed.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

Applicant is relying upon certain biological activities and the disclosure of the limited representative species of a mouse CD40CR antigen (e.g. see Sections 6.2.3 and 6.2.4 as well as Figures 4- 6) to support an entire genus of CD40CR antigens as it reads on mammalian and human CD40CR antigens. The instant invention encompasses any CD40CR antigen as a target of the instant methods, yet the instant specification does not provide sufficient written description as to the structural features of said CD40CR antigen and the correlation between the chemical structure and the function of the genus of CD40CR antigens. Applicant appears to rely upon the disclosure of a limited example of a mouse CD40CR antigen.

While the specification discloses a starting point for screening or testing for molecules that have the characteristics of a CD40CR antigen (e.g. 39 kD protein on helper T cells membranes, which binds to CD40 B cell antigen and stimulates B cell cycle entry); the instant disclosure does not set forth sufficient procedures that will necessarily lead to discovery for such antigens broadly encompassed by the claimed invention and it does not identify a sufficient number of representative members of such mammalian CD40CR antigens (e.g. human CD40 ligand). The application does little more than describe the desired function of the claimed genus of CD40CR antigens broadly encompassed by the claimed invention and does not contain sufficient information by which a person of ordinary skill in the art would understand that the inventors possessed the claimed invention.

While Section 7 of the instant specification discloses binding of CD40Ig to human T cell lines, there was no isolation nor written description of the human CD40CR antigen.

Furthermore, there is insufficient written description of the genus of CD40CR antigens, including as it reads on mammalian CD40CR antigens as well as human CD40CR antigen.

Mere idea or function is insufficient for written description; isolation and characterization at a minimum are required.

In the absence of sufficient guidance and direction to the structural and functional analysis, applicant's reliance upon the mouse CD40CR disclosed as filed does not appear to provide sufficient written description of a genus of distinct molecules of "CD40CR(s)", encompassed by the claimed invention.

The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement make clear that if a claimed genus does not show actual reduction to practice for a representative number of species; then the Requirement may be alternatively met by reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 column 3).

In the absence of structural characteristics that are shared by members of the genus of "CD40CR antigens"; one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus. See University of California v. Eli Lilly and Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997).

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Applicant's arguments have not been found persuasive.

5. Claims 83-86 and 90-94 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for "the protein specifically recognized by monoclonal antibody MR1 produced by the hybridoma having ATCC Accession No. HB 11048" as claimed and disclosed in the instant specification,
does not reasonably provide enablement for
any "antigen having the characteristics recited in instant claims 83-86 (a)-(c)".
The specification does not enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to make and use the invention commensurate in scope with these claims.

Applicant's arguments, filed 9/30/05, have been fully considered but have not been found convincing essentially for the reasons of record.

In certain aspects, particularly as it relates to the certain facts with respect to the disclosure in the specification as filed and those known to the skilled artisan at the time the invention was made,

applicant's arguments and the examiner's rebuttal are essentially the same of record as well as those addressed above in the written description rejection under 35 USC 112, first paragraph.

Applicant asserts that human CD40-Ig is a molecular tool sufficient to enable one of skill in the art to isolate human CD40CR from human T cells as well as murine T cells.

However as pointed out above, it appears that the inventor Noelle relied upon other information, including information derived from another source, that is, Armitage et al. (Nature 357: 80-82, 1992 cited on page of Hollenbaugh et al.). It is noted that that last paragraph of Armitage et al. indicated that cloning of the human homolog was not yet isolated at the time the instant application was filed (i.e. priority date of 2/14/92).

The instant specification only discloses that the mouse CD40CR antigen as claimed, that is, "the protein specifically recognized by monoclonal antibody MR1 produced by the hybridoma having ATCC Accession No. HB 11048"

Also, see the previous Office Action, mailed 3/30/05, for a more complete analysis of the enablement rejection of record.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth.

The specification does not describe nor enable any "CD40CR antigen" broadly encompassed in the claimed methods.

Applicant is relying upon certain biological activities and the disclosure of the limited representative species of a mouse CD40CR antigen (e.g. see Sections 6.2.3 and 6.2.4 as well as Figures 4- 6 of the instant specification) to support an entire genus of CD40CR antigen as it reads on mammalian and human CD40CR antigens. The instant invention encompasses any CD40CR antigen as a target of the instant methods, yet the instant specification does not provide guidance on how to make and how to use the essential structural features of said genus of CD40CR antigens and the correlation between the chemical structure and the function of the genus of CD40CR antigens. Applicant appears to rely upon the disclosure of a limited example of a mouse CD40CR antigen.

While the specification discloses a starting point for screening or testing for molecules that have the characteristics of a CD40CR antigen (e.g. 39 kD protein on helper T cells membranes, which binds to CD40 B cell antigen and stimulates B cell cycle entry); the instant disclosure does not set forth sufficient procedures that will necessarily lead to discovery for such antigens broadly encompassed by the claimed invention and it does not identify a sufficient number of representative members of such antigens (e.g. human CD40 ligand). The application does little more than describe the desired function of the claimed genus of CD40CR antigens broadly encompassed by the claimed invention and does not contain sufficient information by which a person of ordinary skill in the art would be able to make and use the scope of CD40CR antigen specificities broadly encompassed by the claimed invention.

While Section 7 of the instant specification discloses binding of CD40lg to human T cell lines, there is no isolation of the human CD40CR antigen as well as a sufficient number of species to satisfy the enablement of the genus of mammalian CD40CRs encompassed by the claimed invention.

Furthermore, there is insufficient isolation of the genus of CD40CR antigens, including as it reads on mammalian as well as human CD40CR antigen.

The specification describes methods for screening for CD40CR antigens that possess certain desired characteristics and identifies the mouse CD40CR antigen as well as the expectation that other mammalian species similarly express the CD40CR. However, this description without more precise guidelines amount to little more that a starting point, a direction for further research. The specification provides for a plan or an invitation for those of skill in the art to experiment practicing the claimed invention but does not provide sufficient guidance or specificity as to how to execute that plan. It provides a starting point from which one of skill in the art can perform further research in order to practice the claimed invention, but this is not adequate to constitute enablement in that will enable any person skilled in the art to make and use the invention as broadly encompassed by the claimed invention.

In the absence of sufficient guidance and direction to the structural and functional analysis, applicant's reliance upon the mouse CD40CR disclosed as filed does not appear to provide sufficient written description of a genus of distinct molecules of "CD40CR(s)", encompassed by the claimed invention.

Further, as addressed previously and above, it has been noted that parent application USSN 08/742,480 was party to an Interference from the United Stated Patent and Trademark Office Board of Patent Appeals and Interferences (Interference No. 104,415). See Noelle v. Lederman, 69 USPQ2d 1508 (CAFC 2004).

With respect to the disclosure of antibodies that bind a genus of CD40CR antigens, including human CD40CR; the Court affirmed the decision by the Board supported by substantial evidence and the law which held that the USSN 08/742,480 application lacked written description for the genus of CD40CR antigens, including human CD40CR antigen (see Decision, including pages 1508-1509, 1516-1517)

Given the state of the art in the early 1990's described by the expert witnesses and evidence, the Court also affirmed the decision by the Board by finding that one skilled in the art would have lacked a reasonable likelihood of success in isolating human CD40CR antigen given mouse CD40CR antigen, including consideration of Noelle's reliance on various screening methods disclosed in the specification (see Decision, including pages 1516-1517).

Applicant has not disclosed "a fully characterized antigen" as it reads on human CD40CR antigen or the genus of CD40CR antigens encompassed by the claims.

In the absence of sufficient guidance and direction to the structural and functional analysis of a sufficient number of species, the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue to make and use the genus of mammalian "CD40CR antigens" other than the particular mouse CD40CR antigen identified by the MR1 monoclonal antibody.

Applicant's arguments have not been found persuasive.

6. The previous rejections under 35 U.S.C. § 112, first paragraph, with respect to claims 57, 58, 67 and 69-70 have been withdrawn in view of the cancellation of these claims.

7. Claims 83-86 and 91-94 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Lederman et al. (U.S. Patent No. 5,993,816) (see entire document) for the reasons of record.

Applicant's arguments in conjunction with the Noelle Declaration under 37 CFR1.131, filed 9/30/05, have been fully considered but are not found convincing essentially for the reasons of record.

However, the 1.131 affidavit is deficient for several reasons.

To antedate a reference, one must provide either a reduction to practice before the effective date or show conception coupled with diligence to subsequent reduction of practice or to the filing date of the application. Furthermore, the rule requires an averment that the invention was made in the United States.

More importantly and consistent with the issues under 35 USC 112, first paragraph, written description and enablement above, as well as the findings of Noelle v. Lederman, 69 USPQ2d 1508 (CAFC 2004),
the evidence in the 131 Declaration does not support the breadth of CD40CR antigens targeted in the claimed methods, does not support or provide objective evidence that identifying a hybridoma that produces an antibody to a mouse antigen provides sufficient information to direct one to have evidence of an inhibitory anti-CD40L antibody, particularly an anti-human CD40L antibody (given that the human CD40L was not identified and isolated at the by applicant at the time the invention was made and in turn, lead methods of inhibiting B cell activation / immunoglobulin production encompassed by the claims and taught by the prior art.

Although the reference is silent about certain claim limitations, it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). "{i}t is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable". In re Woodruff, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). The mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

On this record, it is reasonable to conclude that the claimed functional limitations would be inherent properties of the referenced methods to inhibit humoral immune responses, B cell activation and immunoglobulin production as well as autoimmunity by 5c8-specific antibodies. The same or nearly the same patients and endpoints are targeted by the same or nearly the same CD40L-specific antibodies. It is noted that Lederman et al. teach human CD40L, while the instant application teaches mouse CD40L. The fact that applicant may have claimed the invention with other characteristics from the method set forth in the prior art does not mean that they are entitled to receive a patent on that method.

Lederman et al. teach methods of inhibiting humoral immune responses, including B cell activation and immunoglobulin production as well as autoimmunity by 5c8-specific antibodies (e.g., see Background of the Invention, columns 10-11, and Example 7 on columns 23-27), including antibody fragments, chimeric, humanized and human antibodies as well as antibody conjugates (columns 6-8) (also, see Claims). The 5c8 specificity is the equivalent of the human CD40 ligand or CD40CR antigen, as encompassed and intended by the instant claims. Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced methods to inhibit humoral immune responses, B cell activation and immunoglobulin production as well as autoimmunity by 5c8-specific antibodies.

Applicant's arguments are not found persuasive.

8. Claims 83-86 and 90-94 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Lederman et al. (U.S. Patent No. 5,993,816) in view of Armitage et al. (U.S. Patent No. 5,961,974) essentially for the reasons of record.

Applicant's arguments in conjunction with the Noelle Declaration under 37 CFR1.131, filed 9/30/05, have been fully considered but are not found convincing essentially for the reasons of record and addressed above in the rejection under 102(e).

Applicant argues that the prior art Lederman et al. does not mention CD40 and therefore there would be no motivation to combine.

However, as pointed out previously, given the ability of helper T cell 5C8-/CD40L-specific antibodies, as taught by Lederman et al. OR the ability of various CD40 antagonists, as taught by Armitage et al. to inhibit various immune responses, including T helper cell-mediated immune responses, including humoral responses; one of ordinary skill in the art at the time the invention was made would have been motivated to generate antibody antagonists, including antibody fragments, chimeric, humanized, human antibodies as well as antibody conjugates, as known by the ordinary artisan and taught by Lederman et al. to the mouse and human CD40L taught by Armitage et al. to similarly target T helper cells in order to inhibit humoral responses, B cell proliferation and immunoglobulin production.

From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments have not been found persuasive.

9. The previous rejection of claims 55-56 under 35 U.S.C. § 103(a) as being unpatentable over Lederman et al. (U.S. Patent No. 5,993,816) in view of Armitage et al. (U.S. Patent No. 5,961,974) as applied to claims 44, 46, 50, 52, 54, 57, 83-86 and 90-94 above and further in view of the art known use of antibody conjugates in inhibiting immune responses by the ordinary artisan at the time the invention was made, as evidenced by Ultee et al. (U.S. Patent No. 4,937,183) has been withdrawn in view of the cancellation of these claims.

10. No claim allowed.

11. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phillip Gambel, Ph.D., J.D.
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May 1, 2006